PREMARKET NOTIFICATION [510(k)] Summary

This Summary of Safety and Effectiveness is prepared in accordance with 21 CFR Part 807.92(c).

1. Company Name:

Chison Medical Imaging Co., Ltd.

No.8, Xiang Nan Road, Shuo Fang, New District, Wuxi, China 214142

Chison Medical Imaging Co., Ltd.

No.8, Xiang Nan Road, Shuo Fang, New District, Wuxi, China 214142

Contact:

Ms. Ruoli Mo

Tel: +86-510-85311707, 85310593

Fax: +86-510-85310726

U.S. Agent:

Leiker Regulatory & Quality Consulting

7263 Cronin Circle Dublin, CA 94568

Contact:

Bob Leiker

Tel: (925) 556-1302 Fax: (866) 718-3819

2. Device Name: CHISON Q8/Q6/ Roll (Portable) Diagnostic Ultrasound System

CHISON iVis 60 & iVis 60 EXPERT/i7 (roll-around) Diagnostic Ultrasound

System

Common/Usual Name: Diagnostic Ultrasound System with Accessories

Classification: Regulatory Class: II

Review Category: Tier II

Classfication Name	21 CFR Section	Product Code
Ultrasonic pulsed doppler imaging system	892.1550	90-IYN
Ultrasonic pulsed echo imaging system	892.1560	90-IYO
Diagnostic ultrasonic transducer	892.1570	90-ITX

2. Marketed Device:

K101236, GE Voluson E6/E8 /E8 Expert Diagnostic Ultrasound System

3. Device Description:

The CHISON Q6 / Q8 / iVis60 / iVis60 / EXPERT / i7 ultrasound system is an integrated preprogrammed color Doppler ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging applications.

The CHISON ultrasound system can be configured either as a portable model (Q6/Q8), or as a roll-around model on wheels (iVis60 / iVis60 EXPERT/i7). These systems are designed with the latest technology, using the same quality procedure as ultrasound systems which have been available in the market for years.

This CHISON ultrasound system is a general purpose, software controlled, diagnostic ultrasound system. Its basic function is to acquire ultrasound echo data and display the image in B-Mode (including Tissue Harmonic Imaging), M-Mode, Pulsed (PW) Doppler Mode, Continuous (CW) Doppler Mode, Color Doppler Mode, Power Doppler Mode, Directional Power Doppler Mode, or a combination of these modes.

The CHISON Q Models and iVis60 Models and i7 Model, have been designed to meet the following product safety standards: NEMA UD 2, NEMA UD 3, IEC 60601-1, IEC 60601-1-2, IEC 60601-2-37, IEC 10993-1.

4. Indications for Use:

The system is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for the evaluation of Fetal (Obstetrics), Abdomen, Cardiac (Adult, Pediatric), Small Organ (Thyroid, testes and breast etc), Peripheral Vascular, Transvaginal, Musculo-skeletal (Conventional and Superficial), Pediatric, OB/Gyn and Urology.

5. Comparison to Predicate Device:

The CHISON Q Models and iVis60 Models and i7 Model are of comparable type and substantially equivalent to the current, GE Voluson E8 Diagnostic Ultrasound System (K101236). All systems transmit ultrasonic energy into patients, then perform post processing of received echoes to generate on-screen display of anatomic structures and fluid flow within the body, and have the same intended uses and basic operating modes as the predicate device. All systems allow for specialized measurements of structures and flow, and calculations.

6. Conclusion:

The CHISON Q Models and iVis60 Models and i7 systems are substantially equivalent in safety and effectiveness to the predicate systems. The systems are intended for diagnostic ultrasound imaging and fluid flow analysis. The systems have the same gray-scale and Doppler capabilities. The systems have acoustic output levels below the applicable FDA limits. The systems are designed to applicable electrical and physical safety standards.

End of 510(k) Summary.



Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

Chison Medical Imaging Co., Ltd. % Mr. Bob Leiker US Agent Leiker Regulatory & Quality Consulting 7263 Cronin Circle DUBLIN CA 94568

JUN 1 4 2012

Re: K120801

Trade/Device Name: CHISON iVis 60EXPERT, Q 6/Q8, i7 Diagnostic Ultrasound Systems

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, and ITX

Dated: May 18, 2012 Received: May 22, 2012

Dear Mr. Leiker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the CHISON iVis 60EXPERT, Q 6/Q8, i7 Diagnostic Ultrasound Systems, as described in your premarket notification:

Transducer Model Number

D3C60L Convex Array	D7L60L Linear Array
D4C40L Convex Array	D7L40L Linear Array
D5C20L Convex Array	D3P64L Phased Array
D6C12L Micro-convex Array	D6P64L Phased Array
D7C10L Micro-convex Array	V4C40L Convex Array
D6C15L Convex Array	D10L40L Linear Array
D7L30L Linear Array	

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Jeffrey Ballyns at (301) 796-6105.

Sincerely Yours,

Janine M. Morris

Acting Director

Division of Radiological Devices

Office of In Vitro Diagnostic Device

Evaluation and Safety

Center for Devices and Radiological Health

Diagnostic Ultrasound Indications For Use

1.3 Indications for Use

The device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal (Obstetrics), Abdomen, Cardiac(Adult, Pediatric), Small Organ (Thyroid, testes and breast etc), Peripheral Vascular, Transvaginal, Musculoskeletal (Conventional and Superficial), Pediatric, OB/Gyn and Urology.

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Division of Radiological Devices
ce of In Vitro Diagnostic Device Evaluation and Safety

510K 120801

Prescription Use √ (Part 21 CFR 801 Subpart D)

Section 1.3

AND/OR

Over-The-Counter Use (21 CFR 801 Subpart C)

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Indications For Use Page 1 of 15

Diagnostic Ultrasound Indications For Use

System:

CHISON iVis 60/ iVis 60EXPERT, Q 6/Q8,i7 Diagnostic Ultrasound Systems

Diagnostic Ultrasound Pulsed Echo System

Diagnostic Ultrasound Pulsed Doppler Imaging System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Č	linical Application	Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	M	PWD	CWD	Color Doppler	Power Doppler	Combined	Other*
Ophthalmic	Ophthalmic								
Fetal Imaging &	Fetal	N	N	N		N	N	Note 1	N
Other	Abdominal	Ν	N	· N	N	N	N	Note 1	N
	Intra-operative (Specify)								
	Intra-operative (Neuro)							-	
	Laparoscopic								
,	Pediatric	N	N.	N	N	N	N	Note 1	N
	Small Organ ^[1] (Specify)	N	N	N		N	N	Note 1	N
	Neonatal Cephalic								·
	Adult Cephalic						,		
_	Trans-rectal								
	Trans-vaginal	N	N	N		N	N	Note 1	N
	Trans-urethral							-	
	Trans-esoph. (non-Card.)						[
:	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1	N
•	Musculo-skeletal (Superficial)	N	Ν	N		N	N	Note 1	N
<u> </u>	Intravascular							<u> </u>	<u> </u>
	Other(Urology)	N	N	N		N	N	Note 1	N
	Other (Ob/GYN)	N	Ν	N		N	N	Note 1	N
Cardiac	Cardiac Adult	N	N	N	N	N	N	Note 1	N
	Cardiac Pediatric	N	N	N	N	N.	N	Note 1	N
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
,	Intra-cardiac							<u> </u>	
	Other (Specify)						_	<u> </u>	
Peripheral Vessel	Peripheral vessel	N	Ν	N		N	N	Note 1	N
	Other (Specify)								

N = new indication; P =

P = previously cleared by FDA;

E = added under this appendix

Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD, B+Power Doppler+PWD Other*: 3-D · 4-D, Tissue Harmonic Imaging, [1] Small Organ: Thyroid, testes and breast etc.

Additional Comments:		·
rescription Use <u>\forall</u>	AND/OR	Over-The-Counter Use
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KIDAGAI	ations For Use	Page 2 of 15

Chison Medical Imaging Co., Ltd. - iVis 60 & Q Series,i7 Diagnostic Ultrasound Systems

System:

CHISON iVis 60/ iVis 60EXPERT, Q 6/Q8,i7 Diagnostic Ultrasound Systems

Transducer:

D3C60L Convex Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application			Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	M	PWD	CWD	Color Doppler	Power Doppler	Combined	Other*
Ophthalmic	Ophthalmic								
Fetal Imaging &	Fetal	Ν	N	N	·	N	N	Note 1	Z
Other	Abdominal	Ν	7	N		N	N	Note 1	N
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ ^[1] (Specify)				·				
	Neonatal Cephalic					-			
1	Adult Cephalic			•					
	Trans-rectal								
	Trans-vaginal								
,	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other(Urology)	Ν	N	N		N	N	Note 1	Ν
	Other (Ob/GYN)	N	N	N	,	N	N	Note 1	N
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)				·				
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel									
	Other (Specify)					T			

Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD, B+Power Doppler+PWD Other*: Tissue Harmonic Imaging, [1] Small Organ: Thyroid, testes and breast etc.					
Other : Tissue riamonic magng, [1] Sman C	organ. Thyroid, testes and orea	ist etc.			
Additional Comments:					
Prescription Use	AND/OR	Over-The-Counter Use			
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Office of In Vitro Diagnostic Device Evaluation and Safety

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N = new indication;

P = previously cleared by FDA;

E = added under this appendix

Chison Medical Imaging Co., Ltd. - iVis 60 & Q Series.i7 Diagnostic Ultrasound Systems

System:

CHISON iVis 60/ iVis 60EXPERT, Q 6/Q8,i7 Diagnostic Ultrasound Systems

Transducer: D

D4C40L Convex Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							-
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	M	PWD	CWD	Color Doppler	Power Doppler	Combined	Other*
Ophthalmic	Ophthalmic								
Fetal Imaging &	Fetal	Z	Z	N		N	Z	Note 1	N
Other	Abdominal	Z	N	N		N	N	Note 1	N
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic			·					
	Pediatric			,					
	Small Organ ^[1] (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
'	Trans-vaginal								
	Trans-urethral						1		
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other(Urology)	N	N	N	Ì.	N	N	Note 1	N
	Other (Ob/GYN)	N	N	N		N	N	Note 1	N
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac			-					·
•	Other (Specify)								
Peripheral Vessel					<u> </u>				
	Other (Specify)	<u> </u>	<u> </u>		1		1		
N = new	indication; P = previously clea	red b	y FD	A;	$\mathbf{E} = \mathbf{i}$	added und	er this app	endix	

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Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD, B+Power Doppler	oppler+PWI
Other*: Tissue Harmonic Imaging, [1] Small Organ: Thyroid, testes and breast etc.	•

Aner*: Tissue Harmonic (maging, [1] Sm	iail Organ: Thyroid, testes and brea	st etc.
Additional Comments:		
rescription Use	AND/OR	Over-The-Counter Use
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tion 1.3 Indications For Use

CHISON iVis 60/ iVis 60EXPERT. Q 6/Q8,i7 Diagnostic Ultrasound Systems

Transducer:

D5C20L Convex Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	М	PWD	CWD	Color Doppler	Power Doppler	Combined	Other*
Ophthalmic	Ophthalmic								
	Fetal								
Other	Abdominal	N	N	N	N	N	N	Note 1	N
	Intra-operative (Specify)								
	Intra-operative (Neuro)							Ĭ	
	Laparoscopic							-	
	Pediatric	Z	Z	N	2	N	N	Note 1	Ν
}	Small Organ ^[1] (Specify)								
1	Neonatal Cephalic								
	Adult Cephalic			<u> </u>	,				
	Trans-rectal								
	Trans-vaginal								Ĺ
	Trans-urethral								
•	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)		1						
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other(Urology)								
	Other (Ob/GYN)			<u> </u>					
Cardiac	Cardiac Adult	Ν	N	N	N	N	N	Note 1	N
	Cardiac Pediatric	N	N	N	N	N	. N	Note 1	N
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac			<u> </u>					ļ <u> </u>
	Other (Specify)								<u> </u>
Peripheral Vessel	<u> </u>	<u> </u>							
	Other (Specify)	<u>L</u>				addad umd			<u> </u>

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E = added under this appendix

Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD, B+Power Doppler+PWD Other*: Tissue Harmonic Imaging, [1] Small Organ: Thyroid, testes and breast etc.

Other": Fissue Hannonic intaging, [1] 5	man Organ. Thyroid, testes and oreas	si etc.
Additional Comments:	•	
Prescription Use√_	AND/OR	Over-The-Counter Use
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P = previously cleared by FDA;

CHISON iVis 60/ iVis 60EXPERT. Q 6/Q8,i7 Diagnostic Ultrasound Systems

Transducer:

D6C12L Micro-convex Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

C	linical Application	Mode of Operation								
General	· Specific	В	M	PWD	CWD	Color	Power	Combined	Other*	
(Track 1 Only)	(Tracks 1 & 3)					Doppler	Doppler	Comomea		
Ophthalmic	Ophthalmic									
Fetal Imaging &	Fetal									
Other	Abdominal									
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ ^[1] (Specify)									
	Neonatal Cephalic				,					
	Adult Cephalic			1						
	Trans- rectal									
	Trans- vaginal	N	N	N		N.	·N	Note 1	N	
	Trans- urethral		-		•			· · · · · · · · · · · · · · · · · · ·		
	Trans- esoph. (non-Card.)				_					
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
•	Intravascular									
	Other(Urology)	N	N	N		N	N	Note 1	N	
	Other (Ob/GYN)	N	Ν	N		N	N	Note 1	N	
Cardiac	Cardiac Adult									
<u>'</u>	Cardiac Pediatric									
	Intravascular (Cardiac)								1	
	Trans-esoph. (Cardiac)									
	Intra-cardiac									
	Other (Specify)								<u> </u>	
Peripheral Vessel							<u> </u>		1	
	Other (Specify)								 	
	indication; P = previously clea	red b	y FD	A;	E = :	added unde	er this apr	endix	•	

Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD. B+Power Doppler+PWD

Other*: Tissue Harmonic imaging, [1] Small Organ: Thyrold, testes an	d breast etc.
Additional Comments:		
Prescription Use	AND/OR	Over-The-Counter Use
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Section 1.3	Indications For Use	Page 6 of 15

CHISON iVis 60/ iVis 60EXPERT, Q 6/Q8,i7 Diagnostic Ultrasound Systems

Transducer:

D7C10L Micro-convex Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Cl	Clinical Application			Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	М	PWD	CWD	Color Doppler	Power Doppler	Combined	Other*			
Ophthalmic	Ophthalmic											
Fetal Imaging &	Fetal							<u> </u>				
Other	Abdominal											
	Intra-operative (Specify)											
	Intra-operative (Neuro)								ļ			
•	Laparoscopic			,								
	Pediatric											
	Small Organ ^[1] (Specify)								1			
	Neonatal Cephalic								1			
	Adult Cephalic							·				
-	Trans- rectal											
	Trans- vaginal	N	N	N		N	N	Note 1	N			
	Trans-urethral		·									
	Traris- esoph. (non-Card.)											
	Musculo-skeletal (Conventional)											
	Musculo-skeletal (Superficial)											
	Intravascular											
	Other(Urology)	N	N	N		N	N	Note 1	N			
	Other (Ob/GYN)	N	N	N		N ·	N	Note 1	N			
Cardiac	Cardiac Adult											
	Cardiac Pediatric											
	Intravascular (Cardiac)			1			-					
	Trans-esoph. (Cardiac)											
	Intra-cardiac				,							
	Other (Specify)											
Peripheral Vessel	Peripheral vessel]					
	Other (Specify)						Ī					

Other*: Tissue Harmonic Imaging, [1] St	11 /	,
Additional Comments:		
Prescription Use <u>√</u>	AND/OR	Over-The-Counter Use
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Section 1.3 Indications For Use

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Section 1.3

CHISON iVis 60/ iVis 60EXPERT, Q 6/Q8,i7 Diagnostic Ultrasound Systems

Transducer:

D6C15L Convex Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

CI	inical Application	Mode of Operation								
General	Specific	В	М	PWD	·CWD	Color	Power	Combined	Other*	
(Track 1 Only)	(Tracks 1 & 3)		<u> </u>			Doppler	Doppler	Comomou		
	Ophthalmic			<u> </u>						
Fetal Imaging &	Fetal	N	N	N		N	N	Note 1	N	
Other	Abdominal	N	N	N	·	N	N	Note 1	N	
	Intra-operative (Specify)									
	Intra-operative (Neuro)				· ·					
	Laparoscopic									
	Pediatric									
	Small Organ ^[1] (Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
·	Trans-urethral									
	Trans-esoph. (non-Card.)			1						
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
	Intravascular									
	Other(Urology)	N	N	N		N	N	Note 1	N	
	Other (Ob/GYN)	N	N.	N		N	N	Note 1	N	
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
	Intravascular (Cardiac)			1						
	Trans-esoph. (Cardiac)									
	Intra-cardiac				<u> </u>			•		
	Other (Specify)				İ					
Peripheral Vessel						<u> </u>				
	Other (Specify)				<u> </u>	1		`		
	indication; P = previously clea	red b	y FD	A:	E = 2	added unde	er this apr	endix		

N	= new	indication:	$\mathbf{P} = \mathbf{r}$	previousl	٦

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Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD, B+Power Doppler+PWD Other*: Tissue Harmonic Imaging, [1] Small Organ: Thyroid, testes and breast etc.

Prescription Use	AND/OR	Over-The-Counter Use
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Indications For Use

CHISON iVis 60/ iVis 60EXPERT, Q 6/Q8,i7 Diagnostic Ultrasound Systems

Transducer: D7L30L Linear Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

CI	inical Application				Mo	de of Oper	ation		
						•			
General	Specific	В	M	PWD	CWD	Color	Power	Combined	Other*
(Track 1 Only)	(Tracks 1 & 3)					Doppler	Doppler	Comonica	
	Ophthalmic						·		
	Fetal							ļ	
Other	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neuro)								l
	Laparoscopic								
	Pediatric								L
	Small Organ ^[1] (Specify)						l		
	Neonatal Cephalic								
	Adult Cephalic								
}	Trans-rectal							,	,
	Trans-vaginal								
	Trans-urethral							· -	
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	Ν	N	N		N ·	N	Note 1	N
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	N
	Intravascular								
	Other(Urology)								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel									
	Other (Specify)								

Ν	=	new	ind	lica	tior	ı;	ľ	= 1
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Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD, B+Power Doppler+PWD Other*: Tissue Harmonic Imaging, [1] Small Organ: Thyroid, testes and breast etc.

Prescription Use	AND/OR	Over-The-Counter Use
(Part 21 CFR 801 Subpart D)	•	(21 CFR 801 Subpart C)
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oe of In Vitro Diagnostic Device Evaluation and Safety

P = previously cleared by FDA;

E = added under this appendix

CHISON iVis 60/ iVis 60EXPERT, Q 6/Q8,i7 Diagnostic Ultrasound Systems

Transducer:

D7L60L Linear Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

CI	inical Application	Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	М	PWD	CWD	Color Doppler	Power Doppler	Combined	Other*
Ophthalmic	Ophthalmic								
Fetal Imaging &	Fetal								
Other	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	Ν	N		N	N	Note 1	N
	Small Organ ^[1] (Specify)	Z	Ν	Ν		N	N	Note 1	Ν
j	Neonatal Cephalic								
	Adult Cephalic					1	·		
	Trans- rectal				٠.				
	Trans- vaginal								
	Trans-urethral				·				
	Trans- esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	Z	Z	Ν		· N	N	Note 1	N
	Musculo-skeletal (Superficial)			·					
	Intravascular		Ţ						
	Other(Urology)								I
1	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)				-				
· ·	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								,
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1	N
	Other (Specify)			<u> </u>	<u> </u>	<u>l</u>		L	<u> </u>

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N =	new	inc	lsca	tion:

E = added under this appendix

Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD, B+Power Doppler+PWD Other*: Tissue Harmonic Imaging, [1] Small Organ: Thyroid, testes and breast etc.

Prescription Use	AND/OR	Over-The-Counter Use
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)
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Section 1.3

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CHISON iVis 60/ iVis 60EXPERT, Q 6/Q8,i7 Diagnostic Ultrasound Systems

Transducer:

D7L40L Linear Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application			Mode of Operation						
General	. Specific	В	M	PWD	CWD	Color	Power	Combined	Other*
(Track 1 Only)	(Tracks 1 & 3)		L			Doppler	Doppler	Comonica	
Ophthalmic	Ophthalmic								
Fetal Imaging &	Fetal	<u>.</u>					,		
Other	Abdominal								
•	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	Z	N	N		N.	N	Note 1	N
	Small Organ ^[1] (Specify)	Z	Ň	N		N	N	Note 1	N
,	Neonatal Cephalic							•	
,	Adult Cephalic								
	Trans- rectal							-	
	Trans- vaginal								
	Trans-urethral					,			
	Trans- esoph. (non-Card.)								
•	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1	N
	Musculo-skeletal (Superficial)								
· ·	Intravascular								
	Other(Urology)								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric		•	1				··· · · · - · · ·	
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)	-		1					
Peripheral Vessel		N	Ν	N		N	N	Note 1	N
	Other (Specify)				· · · · · · · · · · · · · · · · · · ·				

N = new indication;

P = previously cleared by FDA;

E = added under this appendix

Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD, B+Power Doppler+PWD Other*: Tissue Harmonic Imaging, [1] Small Organ: Thyroid, testes and breast etc.

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CHISON iVis 60/ iVis 60EXPERT, Q 6/Q8,i7 Diagnostic Ultrasound Systems

Transducer:

D3P64L Phased Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

CI	inical Application	Mode of Operation					•		
	•								
General (Track I Only)	Specific (Tracks 1 & 3)	В	M	PWD	CWD	Color Doppler	Power Doppler	Combined	Other*
Ophthalmic	Ophthalmic					,		,	
Fetal Imaging &	Fetal								
Other	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
•	Laparoscopic					Ĭ .			
	Pediatric								
	Small Organ ^[1] (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal			,					
	Trans-vaginal								
	Trans-urethral						•		
	Trans-esoph. (non-Card.)	[
	Musculo-skeletal (Conventional)								
•	Musculo-skeletal (Superficial)								
	Intravascular						· · · · · · · · · · · · · · · · · · ·		
	Other(Urology)							-	
	Other (Ob/GYN)								
Cardiac	Cardiac Adult	N	N.	N	N	N	N	Note 1	N
•	Cardiac Pediatric								
	Intravascular (Cardiac)					ì			
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)				<u> </u>				
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								
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Other*: Tissue Harmonic Imaging, [1] Sr	nall Organ: Thyroid, testes and brea	st etc.
Additional Comments:		
Prescription Use	AND/OR	Over-The-Counter Use
(Part 21 CFR 801 Subpart D)	•	(21 CFR 801 Subpart C)
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Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD, B+Power Doppler+PWD

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CHISON iVis 60/ iVis 60EXPERT, Q 6/Q8,i7 Diagnostic Ultrasound Systems

Transducer:

D6P64L Phased Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application			Mode of Operation								
	·			<u> </u>								
General (Track I Only)	Specific (Tracks 1 & 3)	В	М	PWD	. CWD	Color Doppler	Power Doppler	Combined	Other*			
Ophthalmic	Ophthalmic	•										
Fetal Imaging &	Fetal				•							
Other	Abdominal											
	Intra-operative (Specify)				,							
	Intra-operative (Neuro)											
	Laparoscopic											
	Pediatric											
	Small Organ ^[1] (Specify)											
•	Neonatal Cephalic							·	Ì			
	Adult Cephalic		1									
	Trans-rectal			1								
	Trans-vaginal											
	Trans-urethral											
	Trans-esoph. (non-Card.)				,							
	Musculo-skeletal (Conventional)					-						
	Musculo-skeletal (Superficial)											
	Intravascular		•				<u> </u>					
	Other(Urology)						<u> </u>					
	Other (Ob/GYN)											
Cardiac	Cardiac Adult						,					
	Cardiac Pediatric	N	N	N	N	N	N	Note 1	N			
	Intravascular (Cardiac)											
	Trans-esoph. (Cardiac)											
•	Intra-cardiac											
	Other (Specify)								1			
Peripheral Vessel									1			
	Other (Specify)						,					

Other*: Tissue Harmonic Imaging, [1] Si	mall Organ: Thyroid, testes and brea	st etc.
Additional Comments:		
Prescription Use	AND/OR	Over-The-Counter Use
(Part 21 CFR 801 Subpart D)	·	(21 CFR 801 Subpart C)
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Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD, B+Power Doppler+PWD

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CHISON iVis 60/ iVis 60EXPERT. Q 6/Q8,i7 Diagnostic Ultrasound Systems

Transducer: V4C40L Convex Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

C	linical Application	Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	M	PWD	CWD	Color Doppler	Power Doppler	Combined	Other*
Ophthalmic	Ophthalmic		L						
Fetal Imaging &	Fetal	Z	Ν	N		N	N	Note 1	N
Other	Abdominal	Z	N	N		N	N	Note 1	N
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ ^[1] (Specify)								
	Neonatal Cephalic					,			·
	Adult Cephalic								
	Trans-rectal								l
	Trans-vaginal							,	
	Trans-urethral								
•	Trans-esoph. (non-Card.)			_					
	Musculo-skeletal (Conventional)	,							
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other(Urology)	N	N	N		N	N	Note 1	N
	Other (Ob/GYN)	N	N	N		N	N	Note 1	N
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac			1		İ			1
	Other (Specify)							<u> </u>	
Peripheral Vessel									
-	Other (Specify)								T

Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD, B+Power Doppler+PWD

Prescription Use		AND/OR	Over-The-Counter Use
(Part 21 CFR 801 Subpart D)			(21 CFR 801 Subpart C)
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Other*: 3-D. 4-D, Tissue Harmonic Imaging [1] Small Organ: Thyroid, testes and breast etc.

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CHISON iVis 60/ iVis 60EXPERT. Q 6/Q8,i7 Diagnostic Ultrasound Systems

Transducer:

D10L40L Linear Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application			Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	M	PWD	CWD	Color Doppler	Power Doppler	Combined	Other*	
Ophthalmic	Ophthalmic									
Fetal Imaging &	Fetal									
Other	Abdominal									
•	Intra-operative (Specify)								,	
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ ^[1] (Specify)	Ν	N	Z		N	N	·N	N	
	Neonatal Cephalic						,			
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral							-		
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)	N	N	N		. N	N	Note 1	N	
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	N	
	Intravascular									
	Other(Urology)									
	Other (Ob/GYN)								1	
Cardiac	Cardiac Adult									
	Cardiac Pediatric								1	
	Intravascular (Cardiac)								<u> </u>	
	Trans-esoph. (Cardiac)				-		ì			
	Intra-cardiac	•				<u> </u>				
	Other (Specify)									
Peripheral Vessel		N	N	N		N	N	Note 1	N	
	Other (Specify)									

N =	new	inc	lica	ition:

E = added under this appendix

Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD, B+Power Doppler+PWD Other*: Tissue Harmonic Imaging, [1] Small Organ: Thyroid, testes and breast etc.

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Over-The-Counter Use

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